House of Representatives

General Assembly

File No. 189

January Session, 2017

Substitute House Bill No. 7118

House of Representatives, March 23, 2017

The Committee on General Law reported through REP. BARAM of the 15th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2017*):

(a) For the purposes of section 20-579 and this section:

(1) "Biological product" has the same meaning as provided in 42 USC 262;

[(1)**]** (2) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

[(2)**]** (3) "Generic name" means the established name designated in the official United States Pharmacopoeia-National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of said publications;

(4) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has: (A) Licensed and determined to meet the standards for interchangeability pursuant to 42 USC 262(k)(4), or (B) determined to be therapeutically equivalent to another biological product, as set forth in the latest edition of the supplement to the federal Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations";

[(3)**]** (5) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen;

[(4)**]** (6) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

[(5)**]** (7) "Epilepsy" means a neurological condition characterized by recurrent seizures;

[(6)**]** (8) "Seizures" means a disturbance in the electrical activity of the brain; and

[(7)**]** (9) "Antiepileptic drug" means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.

(b) Except as limited by subsections **[**(c), (e) and (i)**]** (e), (g) and (k) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent.

When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) Except as limited by subsections (e), (g) and (k) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a biological product for a prescribed biological product if: (1) It is an interchangeable biological product, and (2) the practitioner has not specified, in the manner described in subsection (e) of this section, that there shall be no substitution for the prescribed biological product.

(d) Not later than seventy-two hours following the dispensing of an interchangeable biological product, the pharmacist shall inform the prescribing practitioner and the patient or a representative of the patient of the substitution of such interchangeable biological product for a prescribed biological product.

[(c)**]** (e) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product or prescribed biological product specified on any prescription form, provided (1) for written prescriptions, the practitioner shall specify on the prescription form that the drug product or prescribed biological product is "brand medically necessary" or "no substitution", (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3)

for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

[(d)**]** (f) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

[(e)**]** (g) A pharmacist may substitute a drug product under subsection (b) or interchangeable biological product under subsection (c) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

[(f)**]** (h) Except as provided in subsection **[**(g)**]** (i) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section or an interchangeable biological product as authorized by subsection (c) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product or interchangeable biological product. If the dispensed drug product or interchangeable biological product does not have a brand name, the prescription label shall indicate the generic name of the drug product or interchangeable biological product dispensed along with the name of the manufacturer of the drug **[**manufacturer or distributor**]** product or interchangeable biological product.

[(g)**]** (i) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug or biological product in the container

unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

[(h)**]** (j) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection **[**(d)**]** (f) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

[(i)**]** (k) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not fill the prescription by using a different drug manufacturer or distributor of the prescribed drug or biological product, unless the pharmacist (1) provides prior notice of the use of a different drug or biological product manufacturer or distributor to the patient and the prescribing practitioner, and (2) obtains the written consent of the patient's prescribing practitioner. For purposes of obtaining the consent of the patient's prescribing practitioner required by this subsection, a pharmacist shall notify the prescribing practitioner via electronic mail or facsimile transmission. If the prescribing practitioner does not provide the necessary consent, the pharmacist shall fill the prescription without such substitution or use of a different drug or biological product manufacturer or distributor or return the prescription to the patient or to the patient's representative for filling at another pharmacy. If a pharmacist is unable to contact the patient's prescribing practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of section 20-616. For purposes of this subsection, "pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy"

does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

(l) Not later than seventy-two hours following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer of the biological product. The entry shall be made in a manner that provides notice to the prescriber and may be made through one of the following means: (1) An interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacy benefit management system, or (4) a pharmacy record. If the entry is not made by any of the means specified in subdivision (1), (2), (3) or (4) of this subsection, the pharmacist shall communicate the biological product dispensed to the prescriber using either facsimile, telephone or electronic transmission, provided such communication shall not be required when there is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed or when a refill prescription is not changed from the product dispensed on the prior filling of the prescription. The provisions of this subsection shall not apply to biological products dispensed by a pharmacy operated by a hospital licensed in accordance with the provisions of chapter 368v.

[(j)**]** (m) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

Sec. 2. (NEW) (*Effective October 1, 2017*) Prior to prescribing a biological product, as defined in section 20-619 of the general statutes, as amended by this act, a prescribing practitioner shall discuss with the patient or a representative of the patient the treatment methods, alternatives to and risks associated with the use of such biological product.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2017*	20-619
Sec. 2	*October 1, 2017*	New section

Statement of Legislative Commissioners:
Section 1(a)(4) was redrafted for accuracy and clarity.

GL *Joint Favorable Subst.*

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

The provisions of the bill are not anticipated to result in a fiscal impact to the state employee or retiree health plan because biological product substitutions are not foreseen given the structure of the pharmacy benefit. Specifically, under the current three-tiered structure (generic, brand, and preferred brand) all biologics are in the preferred brand tier with identical out-of-pocket costs to the consumer. Secondly, the structure of the pharmacy plan does not provide for savings to be passed on to the consumer (e.g. purchaser), which is a condition of substitution in subsection (g) of the bill. The provisions of the bill are not anticipated to result in a fiscal impact to municipal health plans.

There is no cost to the Department of Consumer Protection adopting regulations regarding substituting biological products as the agency has expertise in this area.

The Out Years

The lack of fiscal impact would continue into the future provided the state and municipal employee pharmacy benefit remains the same.

OLR Bill Analysis

sHB 7118

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

SUMMARY

This bill authorizes a pharmacist to substitute a biological product for a prescribed biological product if the substitute is an interchangeable biological product and the prescribing practitioner has not prohibited the substitution. It generally extends to these substitutions existing law's requirements for substituting brand name with generic drugs.

The bill also establishes requirements applicable only to biological and interchangeable biological products. Specifically, before prescribing a biological product, a practitioner must discuss with the patient, or patient's representative, the treatment methods, alternatives to, and risks associated with using a particular biological product. Within 72 hours after dispensing an interchangeable biological product, the pharmacist must inform the prescribing practitioner and patient, or patient's representative, of the substitution. The bill also requires pharmacists to electronically record certain information about the biological products they dispense and make it accessible to prescribing practitioners.

A "biological product" is generally a virus; therapeutic serum; toxin or antitoxin; vaccine; blood or blood component or derivative; allergenic product; protein, but not a chemically synthesized polypetitide; or arsphenamine or a derivative of it, which is used to prevent, treat, or cure a human disease or condition.

The bill makes several technical and conforming changes.

EFFECTIVE DATE: October 1, 2017

BIOLOGICAL PRODUCT SUBSTITUTION

Interchangeability

The bill defines "interchangeable biological product" as a biological product that the federal Food and Drug Administration (FDA) has (1) licensed and determined meets the interchangeability standards under federal law or (2) determined to be therapeutically equivalent to another biological product, as set forth in the latest edition of the supplement to its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (see BACKGROUND).

Under federal law, a biological product is considered interchangeable if the FDA finds that it is (1) biosimilar (i.e., highly similar, other than minor differences in inactive components, and no meaningful differences in safety, purity, and potency) to the original licensed product and (2) expected to produce the same clinical result in any given patient. For biological products administered to a patient more than once, there must be no greater risk of switching between the biological product and the original licensed product than if only the original product is used.

Notification

Within 72 hours after dispensing an interchangeable biological product, the pharmacist must inform the prescribing practitioner and patient, or patient's representative, of the substitution. Unlike existing law for drug product substitutions, the bill does not prohibit pharmacists from using failure to provide this notice as defense to a lawsuit by a purchaser.

Prohibiting Substitutions

Under the bill, practitioners may prohibit substitutions for prescribed biological products in the same way that existing law authorizes them to prohibit substitutions for brand name drugs. Generally, this means that:

1. for written prescriptions, the practitioner must indicate "no substitution" on the prescription form, or indicate that the

prescribed biological product is "brand medically necessary;"

2. for telephoned prescriptions, the pharmacist must write "no substitution" or "brand medically necessary" on the prescription or enter it in the electronic prescription record; and

3. for electronic prescriptions, the prescribing practitioner must select the "dispense as written" code.

No cost savings. Under the bill, as is the case for drug product substitutions, there must be a cost savings to the purchaser for a biological product substitution to occur. If a patient asks, the pharmacist must disclose the savings amount.

Purchaser objection. Like drug product substitutions, the bill also allows purchasers to reject an interchangeable biological product substitution.

Epilepsy or seizure treatment. The bill extends to filling prescriptions for biological products existing law's limitations on filling prescriptions for prescribed drugs to treat epilepsy or prevent seizures. Specifically, it prohibits filling the prescription by using a different manufacturer or distributor unless the pharmacist (1) gives prior notice of the substitution to the patient and the prescribing practitioner and (2) receives written consent from the practitioner.

ELECTRONIC RECORDS

The bill requires pharmacists, or their designees, within 72 hours after dispensing a biological product, to record its name and manufacturer. The information must provide notice to the prescribing practitioner and may be made through:

1. an interoperable electronic medical records system,

2. an electronic prescribing technology,

3. a pharmacy benefit management system, or

4. a pharmacy record.

If an entry is not made by one of the above means, the pharmacist must let the prescriber know, by fax, telephone, or electronic transmission, that the biological product was dispensed. However, no such communication is necessary when no federally approved interchangeable biological product for the prescribed product exists or when a refill prescription is the same as the originally dispensed product.

The bill exempts from these electronic records requirements, biological products that hospital pharmacies dispense.

MISCELLANEOUS PROVISIONS

Labels

As under existing law for drug product substitutions, the bill requires pharmacists to label the prescription containers of dispensed interchangeable biological products with the product name. If the product has no "brand name", the label must include the product's "generic name" and its manufacturer or distributor. But prescribing practitioners may instruct pharmacists to withhold the name of the interchangeable biological product from the prescription label.

Signs

Under existing law, pharmacies must post signs, near counters where prescriptions are dispensed, informing purchasers of the ability to substitute less expensive and therapeutically equivalent drug products. The bill requires pharmacies to amend their signs to include the same information about interchangeable biological products.

Regulations

The bill requires the consumer protection commissioner, with help from the Commission on Pharmacy, to amend the department's regulations to carry out the bill's provisions.

BACKGROUND

Approved Drug Products with Therapeutic Equivalence Evaluations

The *Approved Drug Products with Therapeutic Equivalence Evaluations* publication identifies drug products approved by the FDA on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 17 Nay 0 (03/07/2017)